DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

99 MAY 12 AM 9:49

ASSISTANT COMMISSIONER
FOR PATENTS

Re: Omnicef® Oral Suspension
Docket No.: 98E-0840

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MAY - 5 1999

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,935,507, filed by Warner-Lambert Company, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Omnicef® Oral Suspension, the human drug product claimed by the patent.

The total length of the regulatory review period for Omnicef® Oral Suspension is 2,745 days. Of this time, 2,406 days occurred during the testing phase and 339 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 1, 1990.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on June 1, 1990.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 31, 1996.

   FDA has verified the applicant's claim that the new drug application (NDA) for Omnicef® Oral Suspension (NDA 50-749) was initially submitted on December 31, 1996.

3. The date the application was approved: December 4, 1997.

   FDA has verified the applicant's claim that NDA 50-749 was approved on December 4, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Charles W. Ashbrook
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